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National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20001

Dear Dr. DeSalvo:

I am pleased to submit our comments on behalf of Allscripts to the Office of the National Coordinator for Health IT (ONC) in response to the draft nationwide interoperability roadmap, *Connecting Health and Care for the Nation.* Allscripts, with a platform of clinical and business solutions for ambulatory, acute and post-acute care settings, is relied upon by the largest network of providers – over 180,000 physicians in almost 50,000 different practice locations, 1,500 hospitals and almost ten thousand extended care facilities. It is through our three decades of experience developing and deploying software to this vast network of providers that we are able to submit informed comments today. We believe that it is especially important to hear from companies serving independent and small healthcare organizations, as those who only serve large health systems with simpler or intentionally constrained requirements for interoperability may reflect their clients' silo'd approaches in their own perspectives.

First, we clearly recognize the collaborative approach that informed the creation of this roadmap. Facilitating and supporting interoperability is all about enabling individuals to access the right information at the right time, particularly where information has to move from provider to provider, from provider to public health entity and provider to patient. Generally, we are positive about the draft roadmap, its identified priorities, and the thoughtful approach taken related to both well-established and emerging interoperability technologies.

That said, we are concerned that the timetables reflected in the graphic on page 15, especially in the support of new standards and the dates when providers would be required to implement 2015 certified products. Also, there is some unease about the fact that many of the tasks in this elaborate roadmap are assigned to a new and fairly undefined single governance process that would, if implemented as proposed, have a notably broad scope and authority. We agree that a clear governance framework is important to manage the interoperability life cycle, from high-value use case identification to endorsement of the necessary standards and guidance to enable end-to-end, fully operational interoperability, but we caution against the creation of an unnecessarily large or costly structure.

In addition to our studied contributions to the comments submitted by the Electronic Health Records Association, we offer the following suggestions and responses to ONC's questions within the roadmap.

General

1.1 - Are the actions proposed in the draft interoperability Roadmap the right actions to improve interoperability nationwide in the near term while working toward a learning health system in the long term?

This version of the interoperability roadmap provides an extensive list, often nicely categorized, of all of the interoperability issues and challenges facing the entire healthcare spectrum. However, without a prioritized list of Use Cases, it becomes very difficult to decide whether or not solutions to any of the pieces are approached in the correct order or grouping within the suggested three, six, or ten year periods. Simplistically, then, we agree that over the whole span of 10 years, the interoperability roadmap may indeed reflect the correct actions to help move us towards a learning health system, but the real issues are how to address the immediate three years and the following three years after that. We believe the roadmap can be significantly improved by first prioritizing large groups of Use Cases (we suggest three to eight groups rather than 56 individual Use Cases), and then addressing the actions within three and six year timeframes in order to achieve the goals of the higher priorities.

1.2 - What, if any, gaps need to be addressed?

We note a few different points in response to this question:

- As a nation, we continue to struggle with the proper collection and use of administrative data to enable algorithmic processes for patient matching to be defined and used. To the extent that the interoperability roadmap focuses on send, receive, find and use of clinical data, it leaves gaps in our collective effort to support clinical research and ultimately the learning health system.
- The Common Clinical Data Set as an idea, and as a goal for minimal content exchange, is an excellent approach, but there are gaps in the details, and there should be definitive inclusion of allergy and intolerance events other than medication allergies.
- The roadmap presumes that Certification is sufficient, while omitting the necessity of increased efforts for testing and testing tools. This is a gap that should be addressed with testing specifics defined for each action/actor/transaction/interoperable content exchange.
- There is currently no simple, effective, patient-friendly model for consent, and the interoperability roadmap starts to address some of these issues by identifying the difference between basic and granular choice. The focus on reducing variation is laudable, but we feel that without a more concerted effort there will still be an insurmountable gap here between what is theoretical vs practical for patients to be able to consent to the sharing of their healthcare data. There are specific activities identified for G1 for years 2015-2017 that are useful, but there are gaps in plans for the follow-through in the following years (2018-2024).

1.3 - Is the timing of specific actions appropriate?

We are hopeful that the timing shown in Figure 2, and other places in the text, are preliminary and not reflective of any actual expected timeline based upon the realities of various ballot and review processes. Adjustment of all timelines, based upon HL7 ballots, NPRM Publication, and Final Rule publication will clearly be necessary.

We also believe that the aggressive proposed timings are further challenging because they do not reflect the transition periods necessary in technology adoption / upgrade, such as when new and incompatible content standards are introduced. In fact, planning additional transition time is essential.

Lastly, the principle of incremental interoperability should be maintained, pragmatically reflecting the goal that every participating entity should be able to upgrade their capabilities without any adverse impact upon any other participant. Adherence to this principle would require timelines including ranges for beginning and completing any new phases.

Priority Use Cases

2.1 - Appendix H lists the priority use cases submitted to ONC through public comment, listening sessions, and federal agency discussions. The list is too lengthy and needs further prioritization. Please submit 3 priority use cases from this list that should inform priorities for the development of technical standards, policies and implementation specifications.

Allscripts is an international company with product development and support requirements that cross both geographical and continuum of care boundaries. Accordingly, an internal survey of Use Case priorities within our business units reflected the broad spectrum of our interests. When we attempted to simplify to just three Use Cases, too, we determined that doing so would do a disservice to many of our current clients, providers, other partners, payers, and most importantly, patients. Nevertheless, if we group the Use Cases as we suggested in question 1.1, we can begin to see some consensus:

- Close Loop Referral group - #3, #39
- Send, Find, Retrieve group - #33, #11, #21, #29, #46, #47, #49, #43
- Tracking Orders, Results, Admissions, Discharges group - #6, #8, #9, #40
- Approval of Services, Benefits Management, Prior Authorization group - #23, #24, 25, #54

NOTE – Further refinement/clarity/common definitions are needed in support of these use cases. For example, how is population health measurement defined? Who are ‘individuals’? This type of clarification would be critical to really deriving value from the roadmap.

Governance

3.1 - The draft interoperability roadmap includes a call to action for health IT stakeholders to come together to establish a coordinated governance process for nationwide interoperability. ONC would like to recognize and support this process once it is established. How can ONC best recognize and support the industry-led governance effort?

We support what we believe to be the general intent to have both ONC and all stakeholders vested in governance of our interoperability efforts, but the pathway forward is not clear and needs significant and inclusive additional discussion in order to arrive at a workable and sustainable solution. The view in the interoperability roadmap that a single, new, as yet defined, governance process can and would coalesce in a short timeframe seems unrealistic and not reflective of the depth and breadth of governance-related challenges to data exchange that exist today. Further, we are skeptical about both

the mechanics and the timeline because of the number of tasks that are left undefined in the roadmap with deferral to this new governance body.

Supportive Business, Cultural, Clinical and Regulatory

4.1 - How can private health plans and purchasers support providers to send, find or receive common clinical data across the care continuum through financial incentives? Should they align with federal policies that reinforce adoption of standards and certification?

We note a few different points in response to this question:

- Private health plans and purchasers need to adopt standards and certification requirements, generally. For example, one way that payers can catalyze the data transportation in transitions of care would be to offer standard and more efficient access (i.e. digital) to medical prior authorization capabilities if certain criteria are met for sending and receiving data, which would reduce reimbursement uncertainty and motivate providers to change their behavior.
- To accomplish this at a scale that would deliver value to the industry, payers would need to come together, likely through organizations such as AHIP, to build consensus around how this would be delivered, what standards should be used, etc.
- Alignment with federal policies to reinforce standards and certification via financial incentives would be immensely valuable to the industry, both to providers who are challenged currently by misaligned requirements in various advanced and value-based payment models (private and public), and to vendors who are asked to develop functionality for the same.

Privacy and Security Protections for Health Information

5.1 - What security aspects of RESTful services need to be addressed in a standardized manner?

We are not clear on what, exactly, is being asked here – this needs clarification. Privacy and security of content are generic concepts that are not particularly tied to any given transport protocol or content format. For RESTful transactions, there are certainly well-known, documented and accepted industry standards in place; if there are suspected gaps, we recommend that the questions and issues should address these specifics.

Core Technical Standards and Functions

6.1 - Which data elements in the proposed common clinical data set list need to be further standardized? And in what way?

Several of the concepts in the list of Common Clinical Data Set are simple and well defined, but even in those cases, there are occasional value set issues.

We also note that any United States-defined values, or even mandates for specific content, may not be aligned with or can even conflict with the requirements for the international community. Working on

base core content and standards that are globally relevant first, and against which national extensions may be applied, will serve us all in the long-term.

Some concepts included in the roadmap are arguably more or less complex – for example, allergic reactions vs intolerances, which remains a topic of debate as to whether there is a clinical need to differentiate. The more important element here, however, is recognition that any new data format, such as FHIR Resources, cannot simply be started from scratch for information models behind their specifications – this could, in fact, lead the industry to debate the same issues over again that are still not resolved with the Consolidated CDA.

From the list of Common Clinical Data Set, we believe the following need additional work:

- Smoking Status – the value set continues to change as to the reporting structure between C-CDA R1.1 and C-CDA R2.0 (and the value set could again be different with FHIR)
- Allergies – why is this limited to Medication Allergies? Is it because the value sets for Food, Substance, and Class of Drugs are not agreed upon?
- Care Plan – the coding of Goals and Interventions is not standardized
- UDDI – this needs time to mature
- Notes/Narrative – is this the big "other" bucket?
- Vital Signs – there continues to be debate over what set of observations constitutes valid entries in this section. BMI is a good example that was at one time forbidden.

Regardless of the clinical item type and the value set, we also suggest that there must be more coherent work on how to report pertinent negatives. This is an important issue that needs focus.

6.2 - Do you believe the approach proposed for Accurate Individual Data Matching will sufficiently address the industry needs and address current barriers?

Absolutely not. It is true that the proposed would likely produce approaches that improve the current state, but it is not an approach that will lead to sufficient confidence or resolution of patient safety concerns as compared to other ideas currently being explored by the private sector today.

Certification and Testing to Support Adoption and Optimization of Health IT Products and Services

We believe that much more emphasis on testing, testing data sets, and testing tools should take place and that ONC should shift from reliance on certification as the only means. While it is true that the two are related, we know that certification imitates a final exam whereas a comprehensive set of tests, test data sets, and testing tools actually provides far more beneficial results in truly representing the abilities of the product. Therefore, we recommend moving from the use of specific technologies to testable solutions for meaningfully using content. We would also be supportive of programs and policy that allowed for rapid testing and deployment of small components rather than a program requiring the compete certification of an entire product. Automation of these testing tools should aim to approach a level of robustness that would ensure they could be used repetitively, perhaps as services, for the repetitive processes of daily builds and regression testing. Testing should also be used to ensure that we move forward, as a group, incrementally.

Thank you for the opportunity to provide input on the important topics enclosed. We welcome the chance to speak with anyone within the ONC organization, should you have any questions.

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